Fluticasone Propionate Nasal Spray by Apotex Corp: Recall - Due to Potential for Small Glass Particles

[Posted 05/31/2018]

AUDIENCE: Patient, Pharmacy, Health Professional

ISSUE: The Fluticasone Propionate Nasal Spray 50 mcg per spray 120 Metered Sprays has been found to contain small glass particles. The glass particles could block the actuator and impact the functionality of the pump. The issue was discovered through a customer complaint. There is a potential for patients to be exposed to the glass particles and mechanical irritation cannot be ruled out. Local trauma to the nasal mucosa might occur with use of the defective product. To date, Apotex Corp. has not received any reports of adverse events related to recall.

BACKGROUND: Fluticasone Propionate Nasal Spray is indicated for the treatment of seasonal and perennial allergic rhinitis and for the management of sinus pain and pressure associated with allergic rhinitis in patients 4 to 17 years of age.

RECOMMENDATION: Patients, wholesalers, retailers, hospitals or institutions with Lot# NJ4501 and an expiration date of July 2020, should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall.

If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For additional assistance, call GENCO Pharmaceutical Services, a subsidiary of FedEx Supply Chain (GENCO) at 1- 877-475-5863 (7:00am – 5:00pm, CST Monday thru Friday), to arrange for return of the product.

Customers with questions regarding this recall can contact Apotex Corp. by phone-number 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address **UScustomerservice@Apotex.com (mailto:UScustomerservice@Apotex.com?subject=Recall)**. Customers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**

- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[05/31/2018 - **Recall (/Safety/Recalls/ucm609436.htm)** - FDA]

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